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GB0403702.4

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BOOTS HEALTHCARE INTERNATIONAL LIMITED,
Incorporated in the United Kingdom,
1 Thane Road West,
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[ADP No. 08504136001]

Patents Form 1/77

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference — 1060/773/P/GB

2. Patent application number *(The Patent Office will fill in this part)* — 0403702.4 — 19 FEB 2004

3. Full name, address and postcode of the or of each applicant *(underline all surnames)* — The Boots Company PLC
Nottingham
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SECTION 30 (1977 ACT) APPLICATION FILED

Patents ADP number *(if you know it)* — 40009640003

If the applicant is a corporate body, give the country/state of its incorporation — England

4. Title of the invention — Skincare Compositions

5. Name of your agent *(if you have one)* — Adamson**Jones**

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)* — Broadway Business Centre
32a Stoney Street
Nottingham
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Patents ADP number *(if you know it)* — 07979487001

6. Priority: Complete this section if you are declaring priority from one or more earlier patent applications, filed in the last 12 months.

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. Divisionals, etc: Complete this section only if this application is a divisional application or resulted from an entitlement dispute (see note f)

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8. Is a Patents Form 7/77 (Statement of inventorship and of right to grant of a patent) required in support of this request? *(Answer 'yes' if:*
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
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9. Accompanying documents: A patent application must include a description of the invention. Not counting duplicates, please enter the number of pages of each item accompanying this form:

Continuation sheets of this form	
Description	11
Claim(s)	5
Abstract	0
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10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translation of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for a preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
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11. I/We request the grant of a patent on the basis of this application.

Signature

Date
18 February 2004

12. Name, daytime telephone number and email address, if any, of person to contact in the United Kingdom

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Title – Skincare Compositions

This invention relates to skincare compositions, and in particular to compositions in the form of aqueous gels that may have an astringent or toning effect on the skin.

Astringent compositions are used to "tone" and moisturise the skin. Astringent compositions typically comprise a solvent system including a high proportion of a relatively volatile solvent, most commonly ethanol or isopropyl alcohol. Such compositions may comprise as much as 40% or more alcohol and are commonly of low viscosity.

The low viscosity of the composition means that it spreads easily and well when applied to the skin, but has the disadvantage that the composition may be difficult to apply. As a result, a large proportion of the product may be lost when the composition is transferred from the packaging to the user's hands, and then from the hands to the intended site of application, most commonly the face and surrounding areas. This leads to wastage and may consequently result in dissatisfaction on the part of the consumer. If, alternatively, the composition is applied using an absorbent pad or the like, then large proportions of the composition may be absorbed directly into the pad and again be wasted.

Wastage of the composition may be reduced by increasing the viscosity, eg by formulation of the composition as a gel. However, this has the disadvantage that the composition may be more difficult to apply.

For the above reasons, it would be desirable to develop a skincare composition that is sufficiently viscous to be relatively easy to dispense and handle prior to application, yet which spreads easily upon the intended site of application.

There has now been developed a skincare formulation that substantially satisfies this requirement and/or which overcomes or substantially mitigates the above-mentioned and/or other disadvantages associated with the prior art.

According to the invention, there is provided a skincare composition in the form of an aqueous gel, the composition comprising a thickening agent in the form of a copolymer of acryloyl dimethyl tauric acid or a salt thereof.

The skincare composition according to the invention is advantageous primarily in that it is of sufficient viscosity to facilitate handling and dispensing of the composition, yet flows freely and is readily spreadable when applied to the intended site of application.

According to another aspect of the invention, there is provided a method for the treatment of a person's skin, which method comprises the application to the skin of a skincare composition in the form of an aqueous gel, the composition comprising a thickening agent in the form of a copolymer of acryloyl dimethyl tauric acid or a salt thereof.

The method according to the latter aspect of the invention may have a therapeutic effect, in that it may be useful in the prophylaxis or remedial treatment of a disease or disorder of the skin. Alternatively, the method may be essentially cosmetic in nature, being effective to improve the appearance of the area of the skin to which the composition is applied.

A variety of thickening agents may be used in the composition according to the invention. In general, the copolymer of acryloyl dimethyl tauric acid (or a salt thereof) is a copolymer of that monomer with another vinylic monomer.

Most preferably, the thickening agent is a copolymer of a salt of acryloyl dimethyl tauric acid with another vinylic monomer. The salt may be a salt of a Group I alkali metal, but is more preferably an ammonium salt.

Examples of suitable copolymer thickening agents are:

a) Ammonium acryloyl dimethyl taurate / vinyl pyrrolidone copolymer, ie a copolymer of ammonium acryloyl dimethyl taurate and vinyl pyrrolidone (1-vinyl-2-pyrrolidone). This material is available under the trade name Aristoflex AVC from Clariant GmbH, Functional Chemicals Division, D-65840 Sulzbach, Germany.

b) Ammonium acryloyl dimethyl taurate / Beheneth-25 methacrylate copolymer, ie a copolymer of ammonium acryloyl dimethyl taurate and Beheneth-25 methacrylate, the structure of which is

$$CH_2=CH(CH_3)CO_2\text{-}(CH_2CH_2O)_nCH_2(CH_2)_{20}CH_3$$

in which n is approximately 25. This material is also available from Clariant GmbH under the trade name Aristoflex HMB.

c) Ammonium acryloyldimethyltaurate / vinyl formamide copolymer, ie a copolymer of ammonium acryloyl dimethyl taurate and vinyl formamide. Again, a suitable material is available from Clariant GmbH under the trade name Aristoflex AVC-1.

The composition most preferably comprises less than 10% w/w of the thickening agent, and more commonly less than 5% w/w. The amount of thickening agent will generally be greater than 0.1% w/w and more commonly greater than 0.5% w/w. The amount of thickening agent in the composition will preferably lie in the range 0.1 to 5% w/w, more preferably 0.5 to 5% w/w. Typically, the amount of thickening agent will be less than 3% w/w, eg about 1% w/w or about 2% w/w.

The composition according to the invention preferably has a viscosity of from about 50 mPa.s to about 20,000 mPa.s, more preferably from about 100 mPa.s to about 10,000 mPa.s. Viscosity may be measured using a Brookfield RVT viscometer equipped with a spindle 4 rotating at 10rpm after 2 minutes.

The composition according to the invention has the form of an aqueous gel. As such, the composition will generally comprise a major proportion of water. The amount of water in the composition will typically be in excess of 40% w/w, more commonly in excess of 50% w/w, and may be in excess of 75% w/w.

Most preferably, the composition according to the invention comprises not only water, but also a cosolvent of greater volatility than water. The cosolvent is most preferably an alcohol, particularly ethanol or isopropyl alcohol. Compositions comprising ethanol are particularly preferred.

The composition most preferably comprises in excess of 5% w/w of the cosolvent, and may comprise in excess of 10% w/w, in excess of 20% w/w, or in excess of 30% w/w of the cosolvent. The amount of cosolvent present in the composition preferably does not exceed 50% w/w. The amount of cosolvent thus preferably lies in the range 5% to 50% w/w, more preferably 10% to 50% w/w. In general, higher proportions of cosolvent may be required in compositions containing higher proportions of ingredients (eg topically active ingredients, as discussed below) that are of low solubility in water. Where such ingredients are absent, of their concentration is relatively low, the proportion of cosolvent may also be somewhat lower than in other embodiments, eg up to 20% w/w.

Overall, the concentration of solvent in the composition (ie water and any cosolvent) is preferably in excess of 80% w/w, and may be in excess of 90% w/w. The total amount of solvent in the composition will generally be less than 99% w/w.

The composition according to the invention may comprise one or more topically active ingredients useful in skincare. Such active ingredients may include one or more of the following:

antimicrobial or antibacterial compounds, for example selected from the following:

triclosan, neomycin, clindamycin, polymyxin, bacitracin, benzoyl peroxide, hydrogen peroxide, tetracylines such as doxycycline or minocycline, sulfa drugs such as sulfacetamide, penicillins, cephalosporins such as cephalexin, and quinolones such as lomefloxacin, olfoxacin or trovafloxacin;

antiviral compounds, for example selected from acyclovir, tamvir, and penciclovir;

antifungal compounds, for example selected from the following: farnesol, clotrimazole, ketoconazole, econazole, fluconazole, calcium or zinc undecylenate, undecylenic acid, butenafine hydrochloride, ciclopirox olaimine, miconazole nitrate, nystatin, sulconazole, and terbinafine hydrochloride;

anti-inflammatory compounds, for example selected from the following: steroidal agents selected from hydrocortisone, fluocinolone acetonide, halcinonide, halobetasol propionate, clobetasol propionate, betamethasone dipropionate, betamethasone valerate, and triamcinolone acetonide, and non-steroidal anti-inflammatory agents selected from aspirin, ibuprofen, ketoprofen, naproxen, aloe vera gel, aloe vera, licorice extract, pilewort, Canadian willow root, zinc, and allantoin;

anthelmintic compounds, for example metronidazole;

keratolytic compounds, for example salicylic acid.

The composition according to the invention preferably comprises a keratolytic agent. A particularly preferred active ingredient for inclusion in the composition according to the invention is salicylic acid. Salicylic acid is preferably incorporated into the composition according to the invention as the free acid. However, the pH of the composition may, and generally will, be such that the salicylic acid exists in the composition in dissociated form. As the composition may well contain cationic counterions, the salicylic acid may then be thought of as being present in salt form. Alternatively, the salicylic acid may be incorporated into the composition in salt

form, eg as a salt with a Group I metal, such as sodium salicylate. As used herein, unless the context requires otherwise, any and all references to salicylic acid should be taken to encompass references to the acid and to dissociated forms and salts thereof.

The concentration of salicylic acid in the composition according to the invention is preferably at least 0.1% by weight, more preferably at least 0.5%. The concentration of salicylic acid is preferably less than 5%, more preferably less than 4%, and most preferably less than 3%. The concentration of salicylic acid may therefore fall in the range 0.1% to 5% by weight, more preferably 0.5% to 4%, and most preferably 0.5% to 3%. Particularly preferred concentrations of salicylic acid are 0.5%, 1%, 1.5% and 2% by weight.

The composition may also comprise an antibacterial agent, particularly a peroxide antibacterial agent. A preferred peroxide antibacterial agent for inclusion in the composition is hydrogen peroxide. Alternatively, the composition may comprise a compound that, in use, is capable of generating hydrogen peroxide. An example of the latter class of compound is an adduct such as urea peroxide (carbamide peroxide).

In one preferred embodiment of the invention, the composition comprises both salicylic acid and hydrogen peroxide.

Where hydrogen peroxide is present in the composition according to the invention, the concentration of hydrogen peroxide is preferably at least 1% by weight. The concentration of hydrogen peroxide is preferably less than 5%, more preferably less than 3%, and most preferably less than 2%. The concentration of hydrogen peroxide may therefore fall within the range 1% to 5% by weight, more preferably 1% to 3%, and most preferably 1% to 2%.

The composition according to the invention may additionally comprise other components which will be well known to those skilled in the art. These include, for example:

a) Surfactants – Surfactants may be used in compositions according to the invention as solubilisers, or as cleansing agents or foam boosters. Many different classes of surfactant may be suitable for inclusion in the composition according to the invention, and these will be readily apparent to those skilled in the art. Examples of suitable surfactants include polyethylene glycol ethers of alcohols such as isocetyl alcohol (eg Isoceteth-20), isostearyl alcohol (eg Isosteareth-20), cetyl alcohol (eg Ceteth-20), oleyl alcohol (eg Oleth-20) and cetearyl alcohol (eg Ceteareth-20). A particularly preferred surfactant for use in the invention is Isoceteth-20.

b) Emollients – ingredients that help to maintain the soft, smooth and pliable appearance of skin. Such ingredients may function by their ability to remain on the surface of the skin or in the stratum corneum, and to act as lubricants, reducing or preventing flaking of the skin and improving the skin's appearance. Examples of emollients are isopropyl myristate, triglycerides of fatty acids eg lauric triglyceride or capric/caprylic triglyceride, such as the tri-glyceride available commercially under the trade name Miglyol 810 (Huls UK), and the polypropylene glycol ether of stearyl alcohol known as PPF-15 Stearyl Ether. Particularly preferred emollients are polysiloxane compounds, in particular those known as cyclomethicone, ie cyclic dimethyl polysiloxane compounds that conform to the formula:

$$-(Si(CH_3)_2)_n-$$

in which n has a value between 3 and 7.

c) Humectants or Moisturisers – ingredients intended to increase the water content of the top layers of the skin. Examples of such ingredients are glycerin, 1,3-butylene glycol and propylene glycol.

d) Preservatives – ingredients which prevent or retard microbial growth and thus protect the composition from spoilage. Examples of preservatives include such as propylparaben, bronopol, sodium dehydroacetate, polyhexamethylenebiguanide hydrochloride, isothiazolone and diazolidinylurea.

e) Chelating agents or sequestering agents (sequestrants) – ingredients that have the ability to complex with and inactivate metallic ions in order to prevent their adverse effects on the stability or appearance of the composition. Examples of chelating agents are ethylenediamine tetraacetic acid and its salts, notably the dipotassium and especially the disodium or tetrasodium salt.

f) pH adjusters – Ingredients used to control the pH of the composition. Examples of pH adjusters are inorganic salts such as sodium hydroxide, and organic bases such as triethanolamine. The pH of the composition is preferably in the range of pH 3-6, and more preferably in the range pH 3-5.

g) mattifying agents – Ingredients used to reduce shine and to impart a matt appearance to the skin to which the composition is applied. Such agents commonly comprise particulate, oil-absorbent polymers. A preferred example of a suitable mattifying agent is lauryl methacrylate/glycol dimethacrylate crosspolymer, which is available under the tradename POLYTRAP Q5-6603.

h) Perfumes and colourings.

The invention will now be described in greater detail, by way of illustration only, with reference to the following Examples.

Example 1

Gel Lotion

Ingredients	% w/w
Aqua	to 100%
Alcohol denat.	35%
Isoceteth-20	3.0%
Salicylic acid	2.0%
Hydrogen peroxide (35%)	4.286%
Ammonium acryloyldimethyltaurate/ vinyl pyrrolidone copolymer	2.0%
Sodium hydroxide (30%)	0.4%
Parfum	0.1%
Disodium EDTA	0.005%

Method

Dissolve the salicylic acid into the alcohol. When fully dispersed add the water and the disodium EDTA. Then shear the ammoniumacryloyldimethyltaurate / vinyl pyrrolidine copolymer powder into the alcoholic mixture until lump free. Stir in the isoceteth-20, parfum and hydrogen peroxide, and then adjust the pH to 3 with sodium hydroxide.

Example 2

Gel Lotion

Ingredients	% w/w
Aqua	to 100%
Alcohol denat.	15%
Isoceteth-20	1.0%
Salicylic acid	2.0%
Ammonium acryloyldimethyltaurate/ vinyl pyrrolidone copolymer	1.0%
Sodium hydroxide (30%)	0.202%

Tetrasodium EDTA	0.005%

Method

Dissolve the salicylic acid into the alcohol. When fully dispersed add the water and the tetrasodium EDTA. Then shear the ammonium acryloyldimethyltaurate / vinyl pyrrolidine copolymer powder into the alcoholic mixture until lump free. Stir the isoceteth-20 and parfum into the thickened dispersion, and then adjust to pH to 3 with sodium hydroxide.

Example 3

Gel Lotion

Ingredients	% w/w
Aqua	to 100%
Alcohol denat.	15%
Isoceteth-20	1.0%
Salicylic acid	0.5%
Ammonium acryloyldimethyltaurate/ vinyl pyrrolidone copolymer	1.0%
Sodium hydroxide (30%)	0.202%
Cyclomethicone	3.0%
Lauryl methacrylate/glycol dimethacrylate crosspolymer	0.5%
Tetrasodium EDTA	0.005%

Method

Dissolve the salicylic acid into the alcohol. When fully dispersed add the water and the tetrasodium EDTA. Then shear the ammoniumacryloyldimethyltaurate / vinyl pyrrolidine copolymer powder into the alcoholic mixture until lump free. With continued shearing add the cyclomethicone and lauryl methacrylate / glycol dimethacrylate crosspolymer, and shear until homogeneous. Stir the isoceteth-20

and parfum into the thickened dispersion, and then adjust to pH to 3 with sodium hydroxide.

Example 4

Gel Lotion

Ingredients	% w/w
Aqua	to 100%
Alcohol (99.9%) + t-butylalcohol (0.1%)	11.5%
Glycerin	0.5%
Isoceteth-20	1.0%
Salicylic acid	0.5%
Hydrogen peroxide (35%)	4.28571%
Ammonium acryloyldimethyltaurate/ vinyl pyrrolidone copolymer	1.5%
Hydrolyzed Milk Peptide	0.2%
Sodium hydroxide (30%)	0.4%
Parfum	0.2%
Disodium EDTA	0.005%
Colorant CI 42090 (Blue No 1 FD&C)	0.0003%

Method

Mix the salicylic acid into the alcohol/t-butylalcohol. When the salicylic acid is fully dissolved, mix in the water, glycerin and disodium EDTA. Add the ammonium acryloyldimethyltaurate / vinyl pyrrolidone copolymer with continuous homogenisation. Then add the isoceteth-20, hydrogen peroxide, hydrolysed milk peptide, parfum in the water. Adjust the pH to 3 with sodium hydroxide (30%) and add in the colorant in the form of a pre-made up solution.

Claims

1. A skincare composition in the form of an aqueous gel, the composition comprising a thickening agent in the form of a copolymer of acryloyl dimethyl tauric acid or a salt thereof.

2. A composition as claimed in Claim 1, wherein the copolymer of acryloyl dimethyl tauric acid, or a salt thereof, is a copolymer of that monomer with another vinylic monomer.

3. A composition as claimed in Claim 1 or Claim 2, wherein the the thickening agent is a copolymer of a salt of acryloyl dimethyl tauric acid with another vinylic monomer.

4. A composition as claimed in Claim 3, wherein the salt is an ammonium salt.

5. A composition as claimed in any one of Claims 1 to 3, wherein the thickening agents is selected from the group consisting of:
ammonium acryloyl dimethyl taurate / vinyl pyrrolidone copolymer;
ammonium acryloyl dimethyl taurate / Beheneth-25 methacrylate copolymer; and
ammonium acryloyldimethyltaurate / vinyl formamide copolymer.

6. A composition as claimed in Claim 5, wherein the thickening agent is ammonium acryloyl dimethyl taurate / vinyl pyrrolidone copolymer.

7. A composition as claimed in any preceding claim, wherein the composition comprises less than 10% w/w of the thickening agent.

8. A composition as claimed in Claim 7, wherein the composition comprises less than 5% w/w of the thickening agent.

9. A composition as claimed in any preceding claim, wherein the composition comprises more than 0.1% w/w of the thickening agent.

10. A composition as claimed in Claim 9, wherein the composition comprises more than 0.5% w/w of the thickening agent.

11. A composition as claimed in any preceding claim, wherein the composition comprises an amount of thickening agent in the range 0.1 to 5% w/w.

12. A composition as claimed in any preceding claim, wherein the amount of water in the composition is in excess of 40% w/w.

13. A composition as claimed in Claim 12, wherein the amount of water in the composition is in excess of 50% w/w.

14. A composition as claimed in Claim 13, wherein the amount of water in the composition is in excess of 75% w/w.

15. A composition as claimed in any preceding claim, which comprises a cosolvent of greater volatility than water.

16. A composition as claimed in Claim 15, wherein the cosolvent is an alcohol.

17. A composition as claimed in Claim 16, wherein the alcohol is ethanol.

18. A composition as claimed in any one of Claims 15 to 17, which comprises in excess of 5% w/w of the cosolvent.

19. A composition as claimed in Claim 18, which comprises in excess of 10% w/w of the cosolvent.

20. A composition as claimed in Claim 19, which comprises in excess of 20% w/w of the cosolvent.

21. A composition as claimed in Claim 20, which comprises in excess of 30% w/w of the cosolvent.

22. A composition as claimed in any one of Claims 15 to 21, wherein the amount of cosolvent present in the composition does not exceed 50% w/w.

23. A composition as claimed in any preceding claim, which comprises one or more topically active ingredients useful in skincare.

24. A composition as claimed in Claim 23, wherein said one or more topically active ingredients are selected from the group consisting of:
antimicrobial or antibacterial compounds selected from the following: triclosan, neomycin, clindamycin, polymyxin, bacitracin, benzoyl peroxide, hydrogen peroxide, tetracylines such as doxycycline or minocycline, sulfa drugs such as sulfacetamide, penicillins, cephalosporins such as cephalexin, and quinolones such as lomefloxacin, olfoxacin or trovafloxacin;
antiviral compounds, selected from acyclovir, tamvir, and penciclovir;
antifungal compounds, selected from the following: farnesol, clotrimazole, ketoconazole, econazole, fluconazole, calcium or zinc undecylenate, undecylenic acid, butenafine hydrochloride, ciclopirox olaimine, miconazole nitrate, nystatin, sulconazole, and terbinafine hydrochloride;
anti-inflammatory compounds, selected from the following: steroidal agents selected from hydrocortisone, fluocinolone acetonide, halcinonide, halobetasol propionate, clobetasol propionate, betamethasone dipropionate, betamethasone valerate, and triamcinolone acetonide, and non-steroidal anti-inflammatory agents selected from aspirin, ibuprofen, ketoprofen, naproxen, aloe vera gel, aloe vera, licorice extract, pilewort, Canadian willow root, zinc, and allantoin;
metronidazole; and
salicylic acid.

25. A composition according to Claim 24, wherein the composition comprises a keratolytic agent.

26. A composition according to Claim 25, wherein the keratolytic agent is salicylic acid.

27. A composition as claimed in Claim 26, wherein the concentration of salicylic acid in the composition is at least 0.1% by weight.

28. A composition as claimed in Claim 27, wherein the concentration of salicylic acid in the composition is at least 0.5%.

29. A composition as claimed in any one of Claims 26 to 28, wherein the concentration of salicylic acid is less than 5%.

30. A composition as claimed in Claim 29, wherein the concentration of salicylic acid is less than 3%.

31. A composition as claimed in any one of Claims 25 to 30, wherein the composition also comprises an antibacterial agent.

32. A composition as claimed in Claim 31, wherein the antibacterial agent is a peroxide antibacterial agent.

33. A composition as claimed in Claim 31, wherein the peroxide antibacterial agent is hydrogen peroxide or the composition comprises a compound that, in use, is capable of generating hydrogen peroxide.

34. A composition as claimed in Claim 33, wherein the concentration of hydrogen peroxide is at least 1% by weight.

35. A composition as claimed in Claim 33 or Claim 34, wherein the concentration of hydrogen peroxide is less than 5%.

36. A composition as claimed in Claim 35, wherein the concentration of hydrogen peroxide is less than 2%.

37. A method for the treatment of a person's skin, which method comprises the application to the skin of a skincare composition in the form of an aqueous gel, the composition comprising a thickening agent in the form of a copolymer of acryloyl dimethyl tauric acid or a salt thereof.

38. A method as claimed in Claim 37, which method is a therapeutic method.

39. A method as claimed in Claim 37, which method is a cosmetic method.

40. A method as claimed in any one of Claims 37 to 39, wherein the composition is a composition as claimed in any one of Claims 2 to 36.